26. An allograft,

comprising:

a. preserved vessel isolated from a human placenta directly lyophilized without chemical denaturing, said preserved vessel exhibiting low antigenicity and high patency when implanted as an allograft.

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REMARKS

The above amendment is submitted in response to the Examiner's Action in the parent case, paper number 5.

Applicant has provided a new set of claims 14-26 which is believed to distinguish the invention sought for patenting from the prior art references.

The Examiner rejected the original claims as being unpatentable over Pratt in view of Dardik et al. Other claims were rejected as being obvious over Pratt and Dardik as applied, and further in view of Lau et al and Chin.

Pratt describes arterial allografts and states that previous studies had showed the absence of an immune response with the use of freeze-dried interpositioned allografts. In Pratt's discussion, it was noted that a study by Chow reported freeze-dried microarterial allografts and autografts in rats. Pratt states that freeze-drying only retarded the process of post immune reaction but seem to prevent an immune response to the allografts in the study. Page 704 of the Chow reference states that the patency rate of freeze-dried grafts was as high as 85 percent at

two weeks but dropped to 55 percent in three months. Chow also states that more than 60 percent of the patent grafts showed dilatation with occasional aneurysm formation. Also, most of the blocked grafts became disintegrated at three months due to fibrosis. Thus, it is inaccurate to say that Pratt and Chow show that freeze-dried tissues prevent immune response, since the Chow vessels deteriorated markedly after several months.

Dardik teaches the employment of vessels from the umbilical cord for use in a tubular prosthesis during vascular reconstructive surgery. However, the Dardik the vessel is not one which matches the claim sought for patenting in the present application. Dardik shapes his vessel with a mandrel and soaks the same in glutaraldehyde solution causing hardening. Thus, the Dardik vessel is made rigid through such denaturing or tanning procedures. Also, a polyester mesh is applied to the graft for added support. The Dardik graft vessel is rigid and non-elastic when treated. Dardik, through this tanning procedure has destroyed the integrity of the vessel wall and created a new vessel which is hard and rigid. This vessel is unlike that claimed by Applicant in the present application. Thus, Dardik does not teach Applicant's vessel structure which is directly lyophilized without chemical denaturing.

The addition of Dardik to Pratt would suggest the processing of the Pratt and Chow vessels, by treat them with tanning materials to prevent the lack of patency described in the

Chow reference. Thus, the combination of Pratt and Chow and Dardik would teach away from Applicant's invention which is to take a preserved vessel and directly lyophilize the same without chemical denaturing.

The addition of Lau and Chin concerns the use of nylon stents. However, Lau and Chin add nothing to the teachings of Pratt, Chow, and Dardik which would render Applicant's allograft obvious.

Applicant was the first to devise a preserved vessel allograft in which the vessel is directly lyophilized without chemical denaturing. Although lyophilization was mentioned by Pratt and Chow, the Chow results clearly show that lyophilization did not result in a preserved vessel which exhibited low antigenicity and patency. In fact, the grafts of Chow showed dilation with occasional aneurysm, hardly an auspicious result.

It is believed that the application as amended is in condition for allowance and the passing to issue of the application at an early date is earnestly solicited.

Respectfully submitted,

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